From: Oberman, Dana <DOberman@nabp.net>
To: 'Barry Dickinson (Barry.Dickinson@ama-assn.org)'; "sylvia.trujillo@ama-assn.org' (sylvia.trujillo@ama-assn.org)'; 'daniel.blaney-koen@ama-assn.org'; 'Giacalone, Robert (Robert.Giacalone@cardinalhealth.com)'; Davis, Thomas G.; Ferguson, Betsy; Tankut, Papatya; 'lrobin@fsmb.org'; 'KNicholson@NACDS.org'; 'kbass@pcmanet.org'; "blevy@pcmanet.org' (blevy@pcmanet.org)'; "debbie.garza@walgreens.com' (debbie.garza@walgreens.com)'; "rex.swords@walgreens.com' (rex.swords@walgreens.com)'; "dwayne.pinon@walgreens.com' (dwayne.pinon@walgreens.com)'; 'Schilligo, Nick (NSchilligo@osteopathic.org)'; 'margaret.garikes@ama-assn.org'; 'sandy.marks@ama-assn.org'; 'Janet M Hart (jhart@riteaid.com)'; 'Amy Mullins'; 'alan.must@pharma.com'; 'Ha, Carolyn'
CC: Catizone, Carmen; mike.burleson@ky.gov; 'kryle@partners.org'; 'joeadams98@gmail.com'; 'bill.winsley@me.com'; Madigan, Melissa; Lewalski, Eileen; 'Kenneth Hopson (Kenneth.Hopson@ama-assn.org)'; 'Jeanette Harmon (Jeanette.Harmon@ama-assn.org)'
Sent: 12/18/2013 10:05:38 AM
Subject: FW: Follow-up Stakeholder Meeting on Prescribing and Dispensing Controlled Substances - December 19, 2013
Attachments: Stakeholder Meeting Booklet.pdf

Good morning,

Attached is the electronic version of the booklet that will be distributed at tomorrow's ***Stakeholder Meeting on Prescribing and Dispensing Controlled Substances*** held at the American Medical Association in Washington, DC.

Please feel free to contact us with any questions or concerns.

Regards,
Dana

Dana Oberman
Executive Meeting Planner
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From: Oberman, Dana
Sent: Monday, November 25, 2013 10:27 AM
To: "Barry Dickinson'; 'sylvia.trujillo@ama-assn.org'; 'daniel.blaney-koen@ama-assn.org'; "Giacalone, Robert'; "Davis, Thomas G.'; "Ferguson, Betsy'; "Tankut, Papatya'; 'lrobin@fsmb.org'; 'KNicholson@NACDS.org'; 'kbass@pcmanet.org'; 'blevy@pcmanet.org'; 'debbie.garza@walgreens.com'; 'rex.swords@walgreens.com'; 'dwayne.pinon@walgreens.com'; "Julie Wood'; "Schilligo, Nick'; 'margaret.garikes@ama-assn.org'; 'sandy.marks@ama-assn.org'; "Jane Pyszczynski'; 'Mike A. Podgurski (mpodgurski@riteaid.com)'; 'Amy Mullins'; 'Kenneth Hopson (Kenneth.Hopson@ama-assn.org)'; 'Jeanette Harmon (Jeanette.Harmon@ama-assn.org)'; 'Ha, Carolyn'
Cc: Catizone, Carmen; mike.burleson@ky.gov; 'kryle@partners.org'; 'joeadams98@gmail.com'; Madigan, Melissa; Lewalski, Eileen
Subject: Follow-up Stakeholders Meeting on Prescribing and Dispensing Controlled Substances - December 19, 2013

Good morning:

We are pleased to invite you to attend the follow-up ***Stakeholder's Meeting on Prescription and Dispensing of Controlled Substances*** at the American Medical Association in Washington, DC on ***Thursday, December 19, 2013***. The meeting will take place from 10 am – 2 pm (EST). Due to heightened security measures you are asked to arrive ***10 minutes prior*** to the start of the meeting. Lunch and beverage service will be provided. Please

contact us at your earliest convenience if you have any special dietary requests or allergies. Storage for luggage and a small breakout conference room will also be available if needed.

The American Medical Association is located approximately 5 miles from Washington National Reagan Airport (DCA). Local taxi cab fare runs approximately $15-20 one-way.
Address:
25 Massachusetts Avenue NW, Suite 600 (approximately 1½ blocks from Union Station) **Be sure to mention this information to taxi drivers for address clarification*
Washington, DC 20001
Tel: 202.789.7400

For building clearance measures and for accuracy of counts, we ask that you advise us if you plan on attending this meeting at your earliest convenience or ***by Monday, December 2, 2013***. For those not able to attend in person, call-in capabilities will be available.

Additional information regarding the agenda and background material will be forthcoming prior to the meeting.

Please feel free to contact us with any additional questions or concerns.

Regards,
Dana

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National Association of
Boards of Pharmacy

Stakeholder Meeting on Prescribing and Dispensing Controlled Substances

American Medical Association, Washington, DC

December 19, 2013

Preamble and Mission Statement of the National Association of Boards of Pharmacy

Preamble

The National Association of Boards of Pharmacy (NABP) recognizes and supports pharmacists serving as the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes. NABP also recognizes the ongoing and critical need for patients' medications to be managed by a licensed pharmacist and state regulatory agencies to aggressively enforce standards of care.

NABP Mission Statement

NABP is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP Member Boards of Pharmacy

Alabama State Board of Pharmacy
Alaska Board of Pharmacy
Arizona State Board of Pharmacy
Arkansas State Board of Pharmacy
California State Board of Pharmacy
Colorado State Board of Pharmacy
Connecticut Commission of Pharmacy
Delaware State Board of Pharmacy
District of Columbia Board of Pharmacy
Florida Board of Pharmacy
Georgia State Board of Pharmacy
Guam Board of Examiners for Pharmacy
Hawaii State Board of Pharmacy
Idaho State Board of Pharmacy
Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy
Indiana Board of Pharmacy
Iowa Board of Pharmacy
Kansas State Board of Pharmacy
Kentucky Board of Pharmacy
Louisiana Board of Pharmacy
Maine Board of Pharmacy
Maryland Board of Pharmacy
Massachusetts Board of Registration in Pharmacy
Michigan Board of Pharmacy
Minnesota Board of Pharmacy
Mississippi Board of Pharmacy
Missouri Board of Pharmacy
Montana Board of Pharmacy
Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit
Nevada State Board of Pharmacy
New Hampshire Board of Pharmacy
New Jersey State Board of Pharmacy
New Mexico Board of Pharmacy
New York State Board of Pharmacy
North Carolina Board of Pharmacy
North Dakota State Board of Pharmacy
Ohio State Board of Pharmacy
Oklahoma State Board of Pharmacy
Oregon State Board of Pharmacy
Pennsylvania State Board of Pharmacy
Puerto Rico Board of Pharmacy
Rhode Island Board of Pharmacy
South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy
South Dakota State Board of Pharmacy
Tennessee Board of Pharmacy
Texas State Board of Pharmacy
Utah Board of Pharmacy
Vermont Board of Pharmacy
Virgin Islands Board of Pharmacy
Virginia Board of Pharmacy
Washington State Pharmacy Quality Assurance Commission
West Virginia Board of Pharmacy
Wisconsin Pharmacy Examining Board
Wyoming State Board of Pharmacy

Australia:

Pharmacy Board of Australia*

Canada:

Alberta College of Pharmacists*
College of Pharmacists of British Columbia*
Manitoba Pharmaceutical Association*
New Brunswick Pharmaceutical Society*
Nova Scotia College of Pharmacists*
Ontario College of Pharmacists*
Quebec Order of Pharmacists*
Saskatchewan College of Pharmacists*

New Zealand:

Pharmacy Council of New Zealand*

* Associate Member

Stakeholder Meeting on Prescribing and Dispensing Controlled Substances
American Medical Association, Washington, DC
December 19, 2013

Table of Contents

Stakeholder Meeting on Prescribing and Dispensing Controlled Substances

American Medical Association, Washington, DC
December 19, 2013

Agenda

10 - 10:15 AM	Welcome and Introductions
10:15 - 10:30 AM	Overview of October 2, 2013 Stakeholders Meeting
10:30 - 11:30 AM	Final Approval of the Consensus Statement
Noon - 12:30 PM	Lunch
12:30 - 1:15 PM	Review and Discuss Organizational "Challenges" Documents
1:15 - 2 PM	Review and Discuss Prescribing and Dispensing "Red Flags"
2 PM	Meeting Adjourns

Stakeholder Meeting on Prescribing and Dispensing Controlled Substances

American Medical Association, Washington, DC
December 19, 2013

Attendee List

American Academy of Family Physicians
Amy Mullins, Medical Director for Quality

American Medical Association
Barry Dickinson, Director, Science & Biotechnology
Margaret Garikes, Director, Federal Affairs
Sandy Marks, Assistant Director, Federal Affairs
Sylvia Trujillo, Senior Washington Counsel
Daniel Blaney-Koen, Advocacy Resource Center Senior Attorney

American Osteopathic Association
Nick Schilligo, Director, Division of State Government Affairs

Cardinal Health
Robert Giacalone, Senior VP and Chief Regulatory Counsel

CVS Caremark
Thomas Davis, VP OF Pharmacy Professional Services
Betsy Ferguson, Senior VP and Assistant General Counsel
Papatya Tankut, VP OF Pharmacy Affairs

Drug Enforcement Administration
Joseph T. Rannazzisi, Deputy Assistant Administrator
Alan G. Santos, Associate Deputy Assistant Administrator
Imelda Paredes, Executive Assistant
Robert Hill, Executive Assistant
John Partridge, Executive Assistant

Federation of State Medical Boards
Lisa Robin, Chief Advocacy Officer (observer)

National Association of Boards of Pharmacy
Carmen Catizone, Executive Director
Karen Ryle, President
Michael Burleson, Chairperson
Joseph Adams, President-elect
Melissa Madigan, Policy and Communications Director
Eileen Lewalski, Professional Affairs Senior Manager
William Winsley, Past President

National Association of Chain Drug Stores
Kevin Nicholson, VP of Public Policy and Regulatory Affairs

National Community Pharmacists Association
Carolyn Ha, Director of Professional Affairs

Pharmaceutical Care Management Association
Kristin Bass, SVP Policy and Federal Affairs
Barbara Levy, General Counsel

Pharmaceutical Research and Manufacturers of America
Alan Must, VP of State Government Affairs

Rite Aid
Janet Hart, Director, Government Affairs

Walgreens
Debbie Garza, Divisional VP, Government and Community Relations
Rex Swords, Divisional VP, Pharmacy Services

Stakeholders Consensus Document on Prescribing and Dispensing Controlled Substances

Stakeholders Present:

American Academy of Family Physicians, American Medical Association, American Osteopathic Association, Cardinal Health, CVS Caremark, Drug Enforcement Administration (DEA), Federation of State Medical Boards (observer), National Association of Boards of Pharmacy, National Association of Chain Drug Stores, National Community Pharmacists Association, Pharmaceutical Care Management Association, Pharmaceutical Research and Manufacturers of America, Rite Aid, Walgreen Co.

Background:

The Stakeholders Meeting on Prescribing and Dispensing Controlled Substances met on October 2, 2013, at NABP Headquarters. The stakeholders meeting was convened to discuss the strategies employed by the stakeholder organizations to address the prescription drug abuse epidemic and the actions taken to ensure the validity of controlled substance prescriptions and verify that there is a legitimate medical need for the issuance and dispensing of such prescriptions. Representatives from the participating organizations provided their perspectives on the prescription drug abuse problem and described the challenges faced within their respective practice environments.

Consensus:

The participants agreed that the actions taken by the respective organizations to address the seriousness of the problem and comply with the "corresponding responsibility[1]" requirements of federal and state laws and regulations have inadvertently caused a disruption in the everyday collaboration and coordination among stakeholders. Such collaboration is needed to provide responsible and effective patient care. The participants also recognized that the actions taken were not intended to intrude into the scopes of practice or authority of other stakeholders. Stakeholder representatives discussed the need for reviewing practices and policies they have ~~adopted~~implemented ~~in order to~~ to help ensure that they comply with their legal responsibilities, with the intention of restoring and improving the collaboration and coordination among stakeholders. It was agreed that two consensus documents will be drafted. The first document will identify the circumstances or "red flags" under which actions ~~should~~ may be initiated to ensure the legitimacy of a controlled substance prescription. The second document will provide guidelines on how to engage in and improve dialogue and collaboration among stakeholders, so

Comment [MM1]: AMA

Comment [MM2]: RiteAid

[1] 21 CFR 1306.04 Purpose of issue of prescription. (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

as to address "red flags" in the issuance or dispensing of prescriptions and in the distribution of drugs to practitioners and pharmacies, with the intent of eliminating confusion caused by the diversity of current proprietary policies.

Comment [MM3]: AMA

The American Academy of Family Physicians (AAFP) believes that chronic nonmalignant pain is a health care condition affecting a significant number of Americans leading to economic, social, and medical costs at the individual and system levels. As the use of opioids for pain control has increased, the occurrences of misuse and abuse has risen. Through advocacy, collaboration, research, and education, the AAFP is actively working toward a solution to America's pain management and opioid abuse epidemic.

The official policy of the AAFP can be found here:
http://www.aafp.org/dam/AAFP/documents/patient_care/pain_management/OpioidAbusePositionPaperFINAL.pdf

As the health care delivery system begins to shift towards best-practice prescribing, family physicians face several challenges as prescribers. Several of these challenges are systemic, nation-wide issues. For example:

- The national transition to ICD-10 coding is underway and family physicians are actively engaged in ICD-10 education in order to make the transition possible by the October 2014 deadline.
- The rollout of Meaningful Use phase two has made a real and immediate impact on practice and clinical processes for family physicians across the nation.
- Many family physicians, in both independent and employed settings, are still trying to comply with the new HIPPA guidelines and requirements.

Further, family physicians are actively engaged in more practice-specific challenges such as undertaking the transformation into patient-centered medical homes or participating in accountable care organizations. In the midst of these significant and challenging practice changes, family physicians must retain their focus on patients.

Within this context of urgency and change, when the pharmacy calls to clarify a prescription that was written for a legitimate purpose, family physicians often find the communication intrusive in the face of other priorities. Family physicians do, however, recognize the value of an alert pharmacist using due diligence to protect themselves, physicians, and patients by not filling prescriptions that are abusive or invalid. There are recent examples of pharmacists implementing new monitoring policies and finding that DEA numbers from retired physicians were being used to fill opioid prescriptions.

First and foremost, patients with legitimate pain should get the treatment they need. The patient must remain the focus of efforts while stakeholders work together to foster a solution. As physicians collaborate with other industry stakeholders, there are a number of options that can be explored to facilitate the transition to best practice prescribing. These options could include:

- Re-focus on building the appropriate infrastructure to facilitate the use of electronic prescribing for all controlled substances.
- Develop guidelines for information to be included in prescription forms in order to provide the clarity pharmacists need to circumvent follow up calls to the practice. For example, should physicians include the diagnosis code on the prescription?

- Advocate for the full implementation and funding of the National All Schedules Prescription Electronic Reporting program.
- Develop protocols for the appropriate use of non-physician care team members to address pharmacist inquiries in the case of a follow up call.
- Provide specific and actionable guidance for family physicians to report pharmacists and pharmacy staff not acting in good faith or abusing new fulfillment policies.

Role of the Wholesale Distributor

Legal Requirements

1. Recordkeeping. Distributors are required to make and keep a variety of records such as records of receipt and distribution of controlled substances and inventories.

2. Verification of Registration. Distributors are required to know that the entities to which they distribute controlled are properly registered with DEA or make a good faith inquiry in accordance with 21 CFR §1301.74(a).

3. Reporting. Distributors are required to file a variety of reports with DEA. Most germane to the issue of prescription drug abuse is the requirement that distributors detect and report to DEA suspicious orders for controlled substances in accordance with 21 CFR §1301.74(b). Suspicious orders are "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

DEA Expectations/Guidance Regarding Suspicious Order Monitoring

1. DEA has indicated in guidance letters that distributors must go beyond detecting and reporting suspicious orders and must not fill a suspicious order "without first determining that [the] order is not being diverted into other than legitimate medical, scientific, and industrial channels."

2. DEA has stated in presentations that "A pattern of drugs being distributed to Doctors or Pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the Doctors, the Pharmacies, and the registrants supplying those substances."

3. DEA has stated in guidance letters that it "does not approve or otherwise endorse any specific system for reporting suspicious orders." DEA has indicated that past communications from DEA that could be construed as approval of a particular system for reporting suspicious orders cannot be relied upon by registrants.

Pressures on Distributors

Practitioners and pharmacists are required by DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Distributors are not in a position to determine whether prescriptions are legitimate, but instead are expected to block and report suspicious orders. A significant challenge for distributors is understanding what DEA considers to be a suspicious order. DEA has used national averages for purchases of oxycodone and hydrocodone by pharmacies when evaluating the legitimacy of distributions by distributors to particular pharmacies. However, it is unclear whether DEA considers: the overall size of the pharmacy (e.g., how many prescriptions are filled per day –both controlled and non-controlled substances in relation to controlled substances purchased); any specialty practice within a pharmacy; affiliation(s) with healthcare intuitions such as hospitals or clinics; the type(s) of patient population a pharmacy serves; variations in geographical or regional prescribing patterns which may affect which products are dispensed and purchased; or other factors that influence the volume of controlled substances ordered and the ordering pattern of a pharmacy. While it is evident that a substantial number of pharmacies will order oxycodone and hydrocodone (as well as other controlled and non-controlled substances) in amounts greater than the national average, it is unclear what DEA will accept as a legitimate reason for a pharmacy to order larger volumes of controlled substances. Thus, distributors must make decisions about whether to fill an order for controlled substances based upon what they believe DEA may consider to be suspicious. This has led several distributors to place limits on the

volume of controlled substances they will distribute to customers and, depending on the distributor that the customer chooses, the limits may vary based upon what criteria that distributor uses and how much weight it gives factors within that criteria. As a result, distributors have faced lawsuits and threats of lawsuits from DEA registered pharmacies for either ceasing distribution of controlled substances to the pharmacies or limiting the volumes of controlled substances it will sell.

Distributors would greatly benefit from clarity about how DEA determines whether orders are suspicious and what factors justify a pharmacy's orders for larger than average amounts of controlled substances. Distributors would also benefit from legislative or regulatory action that would protect distributors from lawsuits by pharmacies when a distributor limits or discontinues distributions of controlled substances to a pharmacy as part of the distributor's anti-diversion efforts.

Challenges Facing Physicians

Pain Assessment and Medical Decision-Making

Pain assessment can be straightforward and brief in the setting of acute pain, but increases in complexity as pain becomes persistent, fails to respond to conventional therapy, or occurs in a biomedical or psychological context that pose additional challenges in management. Designing appropriate therapy requires obtaining a detailed history, conducting a physical examination, and assessing pain characteristics, as well as the impact of pain on multiple functional domains, related concerns and comorbidities, and any prior work-up, diagnosis and therapies.

Positioning Opioid Therapy

Because pain is inherently subjective and patient self-reports are the gold standard, pain assessment must be individualized. The population with persistent pain is extremely diverse and there is no one systematic approach to the use of drugs for pain control. Prescription opioid users also are heterogeneous. Among patients with well characterized chronic pain syndromes, some are responsive to the medication and adherent, but others develop problems or complications due to substance use disorders or other conditions. Accordingly, when opioid analgesics are being considered for patients with persistent pain, risks related to prescription drug misuse, addiction, diversion and unintentional overdose should be evaluated using a "universal precautions" approach, and the types of controls built into the treatment plan should be commensurate with these risks. Clinical tools are available to screen patients who may be are at risk for misuse or abuse of prescribed opioids, and in monitoring drug-related behavior during therapy, but these tools are imprecise, which puts an emphasis on a physician's clinical judgment and experience.

Corresponding Responsibility

Most physicians are probably unaware of the "corresponding responsibility" doctrine for pharmacists. While pharmacists have a legal obligation to ensure that prescriptions for controlled substances are issued for a "legitimate medical purpose," most community-based pharmacists are not prepared to evaluate whether a specific pain patient should be managed with opioid analgesics (or for how long), or to independently arrive at a medical decision on such patients that could result in the denial of care. Physician concerns have been amplified by inquiries to explain or justify appropriate medical decisions before a controlled substance is dispensed. Unnecessary encounters that interrupt patient care, and are superimposed on other numerous emerging, ongoing and competing time demands that are essential to maintaining a viable practice are viewed as problematic. These include the Physician Quality Reporting System, Meaningful Use, ICD-10 implementation, Value-Based Modifiers, HIPAA, and the Affordable Care Act, in addition to the adoption of new payment and delivery reform models. Physician education on the legal implications of "corresponding responsibility," professional agreement on appropriate triggers for seeking patient (or physician specific) information, and a pathway for efficient and productive pharmacist-physician (office) interactions are needed.

Prescribing and Dispensing of Controlled Substances: Community Pharmacy's Perspective

NCPA welcomes the opportunity to continue further discussions with stakeholders regarding the Prescribing and Dispensing of Controlled Substances. We appreciate NABP's coordination of these groups for a meaningful discussion, and hopefully some guidance for our respective memberships. Thank you for inviting NCPA to be a part of the initial meeting, we believe that every stakeholder in the supply chain has an important role to play in curbing prescription drug abuse while maintaining appropriate access. We would like to offer the following perspective and impact on community pharmacy as our dialog continues:

- NCPA supports proposals that would require prescribers to obtain additional education or certification on understanding addiction to and abuse of controlled substances and their appropriate and safe use.

- Pharmacies believe that PDMPs can be more effective as they move toward real-time reporting systems and integration into pharmacy workflow processes. However, today's PDMP systems are not able to detect doctor shopping because of lags in data reporting, in addition to the dearth of prescribers who actually use the systems before a prescription is written. We fully support efforts to enhance existing PDMP infrastructure, such as NABP's efforts via PMP InterConnect to link disparate PDMPs and provide for more robust information sharing.

- The DEA states that their increased efforts to block the diversion of prescription drugs to the black market by using many of the techniques it employs to combat illegal drug use have resulted in a substantial dismantling of "pill mills". NCPA appreciates these efforts as we believe that inappropriate prescribing is a primary culprit of the overall problem. However, NCPA has serious concerns with the fact that the DEA is now using the same tactics to prosecute the legitimate pharmaceutical supply chain, including increased inspections and fines against drug wholesalers, which ultimately leads to severe consequences for independent community pharmacies.

  These consequences include wholesalers cutting off all controlled substance supplies to certain legitimate independent pharmacies, with prescription orders of controlled substances going unfilled. Many independent pharmacies cannot obtain medications for their patients, and are fearful and reluctant to service legitimate patients in pain. The wholesalers are being targeted for failure to detect "suspicious" order volume from several pharmacy customers. For example, over the past several years, a large wholesaler has publicly stated they have cut supplies of controlled substances to more than 375 customers nationwide, including 180 pharmacies in Florida. Every one of these customers is an independent pharmacy and nearly 70 percent still have active DEA registration numbers. NCPA contends the fact that so many of these pharmacies still have their registrations means that more clarity is needed from the DEA as to what constitutes excessive orders.

  Independent pharmacies that have had controlled substance orders halted by their wholesaler have relayed to NCPA that there is no consistent reasoning behind what constitutes excessive orders. Some wholesalers refer to reasons such as ratios of controlled to non-controlled substances, dosage units per month, specific spikes in volume, and dollar amount of orders. These wholesaler actions have put many independent pharmacies in the untenable position of having to find a back-up wholesaler quickly, oftentimes while having to legally challenge their wholesaler decision to halt controlled substance deliveries. Unfortunately this is causing hardships for independent pharmacies

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that are primarily located in and serve more rural populations. There is a perception that independents are being targeted for reasons beyond their control such as a lack of ability to self-warehouse, perceived less stringent internal controls, and/or decreased legal capabilities, among others. The DEA must recognize that their actions on wholesalers are having detrimental impacts on legitimate small-business independent community pharmacy owners who are practicing pharmacy to the full extent authorized under the law.

Thank you for consideration of our comments, we look forward to continued collaboration on these important issues.

Community Pharmacy-Based Controlled Substance Dispensing

Community pharmacists are front-line healthcare providers and are one of the most accessible members of a healthcare team. In providing neighborhood care, pharmacists have a strong ethical duty to serve the needs of their patients. Yet, the current healthcare and law enforcement systems of the United States require pharmacists to take on diverse and sometimes conflicting roles. Tension between these dual roles occurs because community pharmacists provide critical medication management and preventive and wellness care to patients, including ensuring that legitimate pain patients receive the much needed care.

Under federal law, pharmacists are also required to be evaluators of the legitimate medical use of controlled substances. In order for a prescription for a controlled substance to be valid, federal law (21 C.F.R § 1306.04(a)) requires that the prescription be issued for a legitimate medical purpose by a prescriber acting in the usual course of his or her practice. The rule places a ***corresponding responsibility*** upon the dispensing pharmacist to establish the validity of the prescription by ensuring the prescription is written for a legitimate medical purpose. To that end, community pharmacists find themselves enaging in inititaives to balance these diverse roles, and are encountering numerous system barriers.

Accordingly, if the stakeholders are to make a meaningful difference regarding prescription drug abuse, the focus must now shift to one of collaboration – collaboration to remove system barriers and provide education programming to healthcare professionals and patients.

THE NEED FOR STRONGER COLLABORATION TO IMPROVE PATIENT CARE

Information Barriers: Community pharmacies and pharmacists are required to provide oversight of prescriptions for controlled substances.[1] Specifically, to ensure a controlled substance prescription is for legitimate medical use, and to fulfill his or her corresponding responsibility, a pharmacist must often evaluate the prescription in the context of the patient's broader medication and medical history. Yet, in many instances, they lack access to relevant information and data. Examples include: lack of knowledge regarding the patient's legitimate medical diagnosis; lack of information concerning the prescriber's practice and philosophy concerning the prescribing of controlled substances; whether a person of interest is using multiple prescribers and/or multiple pharmacies to secure controlled substances, among other matters.

1. **Healthcare Collaboration**: Pharmacists and prescribers must work closely together to ensure each prescription is for a legitimate medical purpose. DEA cases have outlined a number of red flags that may suggest inappropriate use of controlled substances. When various red flags are encountered, pharmacists may need to discuss these circumstances directly with the prescriber to ensure that the red flags can be resolved so that legitimate pain patients are not wrongfully turned away. Strong collaboration and communication is critical. Yet, thus far, collaboration between healthcare professionals has often been

[1] 21 C.F.R § 1306.04(a)

extremely weak.

2. **Information Aggregation - National Database**: To assist with assessments of questionable patients and doctors of interest, stakeholders must strongly support the establishment of a national, aggregated controlled substance database and corresponding efforts.

   While Prescription Drug Monitoring Programs (**PDMPs**) are a good first step, not all states have a program in place. Additionally, some states do not permit pharmacist access to PDMPs, nor do they allow delegation of certain tasks to other pharmacy personnel, limiting effective use. Other states do not have adequate, stable funding for PDMPs. Additionally, there is a need for national interoperability of state PDMPs. Interoperability will only be successful if the state PDMPs reside on a technology infrastructure that can support high utilization with fast (i.e. millisecond) response times. Concern exists with the current ability of existing state technology infrastructure systems to provide this support. Resources and efforts over the last ten (10) years have made some progress; but more efforts are essential. Accordingly, continued resources should be brought to bear to fix the identified system deficiencies and to create a much needed comprehensive, nationally database.

   A viable, parallel approach to creating a national, **uniform data monitoring system** is the expansion and accelerated use of **e-prescribing for controlled substances**. E-prescribing holds great promise to generate a robust database of real-time information that could be used by DEA, state enforcement officers, pharmacies, insurers, wholesalers, and other partners to assist with the proactive identification of prescription drug abuse. E-prescribing may additionally mitigate prescription forgeries, provide a deterrent effect for prescribers, and may eventually be integrated with PDMP data to allow immediate insights at the point of prescribing. Unfortunately, several states prohibit the e-prescribing of controlled substances despite support from the DEA. Further, not all prescribers have embraced e-prescribing, limiting the potential for this robust real-time database. New York is the first state to mandate the electronic prescribing of controlled substances and all states should immediately follow this lead.

3. **Educational Programming:** NACDS is currently developing education programs for frontline pharmacists to better understand red flags and key considerations. Recently, public health organizations have called for similar enhanced education and training requirements for prescribers to assist with curbing prescription drug abuse.

4. **Collaboration with Federal Government:** Pharmacists must also ensure prescriptions are from prescribers operating under their scope of practice, and that they hold an active DEA registration. DEA does not currently provide reliable, consistent and clear data that serves as the ultimate source for decisions surrounding prescriber verification. This database should also provide notice when one state revokes a prescriber's license. **DEA also conducts inspections of regulated facilities** within the broader channel to determine compliance with the Controlled Substances Act (CSA) and implementing regulations. Such oversight is essential to protect the public health, and ensure industry

compliance. Yet, the agency faces criticism for its alleged lack of guidance and transparency. There is a need to promote greater stakeholder accountability, transparency and consistency with respect to the agency's expectations of healthcare professionals, as well as with its inspection and enforcement programs. In addition, DEA should routinely update the industry on emerging trends and new red flags that they are seeing in their cases.

PhRMA: Select Policy Challenges Related to Addressing Prescription Drug Abuse

In recent years the misuse and abuse of prescription medicines has emerged as a growing public health problem. PhRMA and its members are actively engaged in a broad range of efforts with health care providers and other stakeholders to support appropriate use of medicines and ensure patient access to needed medicines. When used appropriately and under the direction and care of a licensed health care professional, prescription medicines can improve and save lives. However, prescription medicines can cause negative health consequences if they are used inappropriately and not as intended.

Below we've highlighted just a few recommendations to be considered to ensure appropriate use of prescription medicines and prevent their diversion, misuse and abuse.

Increasing the Effectiveness of Prescription Drug Monitoring Programs (PDMPs): Effective PDMPs are a crucial component to combating prescription drug diversion. While 49 states have enacted state legislation for PDMP programs, a range of enhancements are needed to improve their effectiveness including but not limited to efforts to improve interoperability between prescriber and pharmacy systems, increased adoption of e-prescribing and use of electronic health records as part of broader efforts to reduce reporting burden on prescribers and pharmacies. In addition, PDMPs should be housed in public health versus law enforcement agencies or public safety departments at the state level and appropriate clinical oversight should be applied to the review and interpretation of PDMP data.

Ensuring Legitimate Patient Access is Not Impeded/Delayed: Some pharmacy chains and state laws have implemented policies to curb "doctor shopping," in order to prevent consumers from trying to fill prescriptions that are not for legitimate use or patients going to multiple providers to fill the same prescription. Pharmacies recognize this behavior and want to be responsible in preventing abuse so some chains have developed policies where pharmacists must first question patients and at times, even call and question their providers about the prescription before they fill the medication for the patient. These policies need to be carefully reviewed and assessed to ensure that they do not unintentionally restrict legitimate patient access, delay patient care, or pose substantial additional administrative burdens and prescribing hurdles on providers.

Ensuring Appropriate Education for Health Care Providers: Providers, state medical societies, and specialty groups, including non-physician prescribers such as dentists, should regularly review and assess the adequacy of current clinical guidelines as well as existing training and educational opportunities and potential enhancements aimed at (1) assuring continued legitimate access to medicines for those with a clinical need, (2) identifying potential fraud, diversion, misuse, and abuse, and (3) appropriately educating patients regarding appropriate use, secure storage, and safe disposal.

DEA Standards And "Red Flags"

This document provides a brief overview of DEA's "corresponding responsibility" standard that applies when pharmacists dispense controlled substances. The document also lists several "red flags" that DEA believes pharmacists must investigate and resolve before dispensing controlled substances. In particular, the red flags listed below arose in the context of DEA investigations of pharmacies, in which DEA alleged that pharmacists failed to exercise their corresponding responsibility.. The following is not an exhaustive list of all DEA standards and red flags.

I. Standards

21 C.F.R. § 1306.04(a) lays out a pharmacist's obligation when dispensing a controlled substance prescription: "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."

DEA interprets 21 C.F.R. § 1306.04(a) "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'" *East Main Street Pharmacy,* 75 FR 66149, 66163 (Oct. 27, 2010).

To prove a violation of 21 C.F.R. 1306.04(a), DEA is "required to prove the following elements: (1) That 'the Respondent dispensed a controlled substance'; (2) that 'a red flag was or should have been recognized at or before the time the controlled substances was dispensed'; and (3) that 'the red flag was not resolved conclusively prior to the dispensing of the controlled substance.'" *Holiday CVS, LLC*, 77 FR 62316, 62321 (Oct. 12, 2012).

Pharmacists have a "responsibility 'to exercise professional judgment' before dispensing prescriptions for highly abused controlled substances." *Holiday*, 77 FR at 62321. This includes "paying attention to the 'number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment,' the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse." *Medicine Shoppe-Jonesborough v. DEA*, 2008 WL 4899525 (2008) (6th Cir.) at *3 (internal citations omitted). If suspicions are aroused, the prescription's propriety must be verified or it should not be dispensed. *Id.*

A pharmacy's DEA registration may be revoked if continued registration is "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). In determining the public interest, DEA considers

factors such as "the applicant's experience in dispensing … controlled substances" and "conduct which may threaten the public health and safety." 21 U.S.C. § 823(f).

II. POTENTIAL "RED FLAGS" -- PATIENT & PHYSICIAN CONDUCT

A. PATIENT CONDUCT

- Patient travels long distance to physician and/or pharmacy.
  - *Holiday,* 77 FR at 62318-19; *East Main,* 75 FR at 66163-64.

- Patient pays with cash.
  - *Holiday,* 77 FR at 62318-21, 62331; *East Main,* 75 FR at 66164.

- Patient uses "street names" when discussing controlled substances.
  - *Holiday,* 77 FR at 62321.

- Patient statements and conduct suggest abuse of controlled substances.
  - *Holiday,* 77 FR at p. 62320; *Holiday CVS, LLC v. Holder,* 839 F.Supp.2d 145, 160 (D.D.C. 2012)' *East Main,* 75 FR at 66151' *East Main,* 75 FR at 66164; *Townwood Pharmacy,* 63 FR 8477, 8478 (Feb. 19, 1998).

- Patients have suspect relationships with each other, e.g., a group of patients obtain the same prescription for the same controlled substances from the same physician.
  - *Holiday,* 839 F.Supp.2d at 161; *East Main,* 75 FR at 66164.

- Evidence of "doctor shopping."
  - *Grider Drug,* 77 FR 44070, 44097 (July 26, 2012); *East Main,* 75 FR at 66165; *Medicine Dropper,* 76 FR 20039 (Apr. 11, 2011); *Jonesborough*, 2008 WL 4899525, at *4; *Medicine Shoppe - Jonesborough*, 73 FR 364, 370-371 (Jan. 2, 2008).

B. PHYSICIAN CONDUCT

- Physician writes large number or percentage of prescriptions for controlled substances
  - *East Main,* 75 FR at 66164.

- Prescribing "high alert" drugs.
  - *Holiday,* 77 FR at 62322; *East Main,* 75 FR at 66159.

- Prescribing questionable "cocktails" of commonly diverted drugs.
  - *Holiday,* 77 FR at 62319; *East Main,* 75 FR at 66163.

- Prescribing combinations of drugs that can cause medical complications.
  - 21 CFR 1306.04(a); *East Main,* 75 FR at 66163; *Jonesborough*, 2008 WL 4899525, at *4; *Jonesborough*, 73 FR at 370.

- Overprescribing large doses of controlled substances to patients.

- *East Main,* 75 FR at 66163-64; *Medicine Dropper,* 76 FR at 20039; *Jonesborough*, 73 FR at 382.

- Recurring pattern of prescribing the same controlled substances to multiple patients, which suggests the physician is operating a pill mill.
  - *Holiday,* 77 FR at 62318; *East Main,* 75 FR at 66163.

- Physician no longer holds DEA registration.
  - *Bob's Pharmacy And Diabetic Supplies,* 74 FR 19599, 19601 (Apr. 29, 2009); *Holiday,* 77 FR at 62316; *Jonesborough*, 73 FR at 368.

- Physician engages in the unauthorized practice of medicine or operates outside area of specialty.
  - *See Liddy's Pharmacy, LLC,* 76 FR 48887 (Aug. 9, 2011); *Sun & Lake Pharmacy, Inc.*, 76 FR 24523 (May 2, 2011); *Bob's Pharmacy And Diabetic Supplies,* 74 FR at 19601; *Meetinghouse Community Pharmacy, Inc.,* 74 FR 10073 (March 9, 2009); *United Prescription Services, Inc.,* 72 FR 50397 (Aug. 31, 2007); *Jonesborough*, 73 FR at 368.

- Location in places such as Florida which have "pill mill" problems.
  - *Holiday* at p. 62322. *See also Holiday,* 839 F.Supp.2d at 159; *Physicians Pharmacy, LLC,* 77 FR 47096 (Aug. 7, 2012).

Respondent's application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that the pending application of George Mathew, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective November 26, 2010.

Dated: October 17, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–27094 Filed 10–26–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–48]

East Main Street Pharmacy; Affirmance of Suspension Order

On April 23, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to East Main Street Pharmacy ("Respondent"), of Columbus, Ohio. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BE5902615, as a retail pharmacy, as well as the denial of any pending applications to renew or modify its registration, "for reason that [Respondent's] continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4)." ALJ Ex. 1, at 1. More specifically, the Order alleged that Respondent had violated its corresponding responsibility under Federal regulations to not fill unlawful prescriptions. *Id.* at 2 (citing 21 CFR 1306.04(a)).

The Show Cause Order alleged that Respondent was owned by Eugene H. Fletcher, Respondent's sole pharmacist, and that from "September 2005 through February 2006" it "filled 6,619 controlled substance prescriptions" including 4,979 prescriptions issued by Dr. Paul Volkman of Portsmouth, Ohio. *Id.* at 1. The Show Cause Order further alleged that on February 10, 2006, DEA had immediately suspended Volkman's registration and that the Agency subsequently found that he had "'repeatedly violated Federal law by prescribing controlled substances without a legitimate medical purpose and outside the course of professional practice.'" *Id.* (citing *Paul H. Volkman,* 73 FR 30630, 30642 (2008)). The Order also alleged that "Dr. Volkman directed his patients to have their prescriptions filled at" Respondent, who "filled them mostly in exchange for cash," and that "[n]inety-eight percent of Dr. Volkman's patients that filled their prescriptions at [Respondent] did not reside in the Columbus area." *Id.* Relatedly, the Order alleged that some of Volkman's patients travelled from Portsmouth and Chillicothe, Ohio to Respondent, a distance of 92 and 45 miles, respectively; that one of Volkman's patients had travelled from South Central Kentucky to Respondent to obtain his prescriptions, that many of Volkman's patients were obtaining prescriptions from other physicians, and that several of these persons died of overdoses. *Id.* at 2.

The Show Cause Order further alleged that Respondent "filled prescriptions for combinations of controlled substances and the non-controlled, but highly addictive drug carisoprodal [sic] (Soma), under circumstances indicating that the prescriptions were issued outside the usual course of professional practice." *Id.* at 2. More specifically, the Order alleged that Respondent filled for numerous patients of Volkman, "large quantity prescriptions" for a benzodiazepine, two narcotic pain medications, and Soma, and that "[t]hese drug combinations are generally known in the medical and pharmacy profession as being favored by drug-seeking individuals." *Id.* The Order also alleged that Respondent "filled several of the above combination prescriptions when the patients should have had two to three weeks' supply of medication from a previous prescription" and it either "did not recognize, or ignored these indicators of drug diversion and abuse." *Id.*

Finally, the Order alleged that, with regard to Dr. Volkman's prescriptions, Mr. Fletcher had told a DEA Investigator "that it was 'not [his] job to question a physician.'" *Id.* Based on the above, the Order alleged that Respondent "knew, or should have known that [the] controlled substance prescriptions it filled for patients of Dr. Volkman were for no legitimate medical purpose." *Id.*

on an opinion of an Investigator who lacked adequate information to properly assess his credibility. Moreover, the inconsistency between Respondent's claim that in prescribing for eDrugstore he only wrote a "small minority" of controlled substance prescriptions and the evidence regarding the total number of prescriptions, the amounts he was paid for the respective types of prescriptions, and his compensation, provides further reason to question the ALJ's conclusion.

The ALJ also found it significant that the Agency had not produced any evidence that Respondent mishandled controlled substances since the institution of the proceeding. However, because Respondent failed to file a timely renewal application, thus allowing his registration to expire (and also had his State license suspended), he lacked authority to handle controlled substances for a substantial portion of this period. In addition, the weight to be given this circumstance is significantly diminished by the fact that he was then in the midst of a Show Cause Proceeding.

Finally, the ALJ did not cite any evidence to support her belief that "this proceeding has instilled in the Respondent a grave respect for the authority and responsibility which attach to his DEA registration." ALJ at 32. Given the egregious misconduct proved on this record, rather than take a leap of faith, I rely on the Agency's longstanding rule which requires that a registrant acknowledge his misconduct and the relevant evidence or, as in this case, the lack thereof.

[1] Therein, Respondent denied the allegations maintaining that "Mr. Fletcher, based on his experience, training, and expertise, reasonably believed that all prescriptions filled were for a legitimate medical purpose" and that he "frequently exercised independent judgment to determine if the prescriptions were for legitimate medical purposes, and often refused to fill prescriptions written by licensed medical doctors, including Dr. Volkman." ALJ Ex. 2, at 2.

REDACTED

Pursuant to my authority under 21 U.S.C. 824(d), on November 10, 2009, I further ordered that Respondent's registration be suspended immediately because its "continued registration * * * constitutes an imminent danger to the public health and safety." ALJ Ex. 8, at 1. The Immediate Suspension Order incorporated by reference the allegations of the Order to Show Cause and cited the additional allegations that Respondent had recently filled more prescriptions for controlled substances for two persons who were travelling substantial distances to obtain the drugs. *Id.* at 1–2.

More specifically, the Immediate Suspension Order alleged that on October 2, 2009, L.D.C., a resident of Portsmouth, Ohio obtained from a physician practicing in Wheelersburg, Ohio, prescriptions for 90 tablets of oxycodone 30 mg. and 60 tablets of carisoprodol (a non-controlled but highly abused drug which metabolizes into meprobamate, a Schedule IV depressant), and that she then travelled "approximately 100 miles from Wheelersburg to Columbus" and filled the prescriptions at Respondent. *Id.* at 2. The Order alleged that the next morning, L.D.C.

REDACTED

The Immediate Suspension Order also alleged that on various dates including July 3, September 1, and October 1, 2009, Respondent had filled various prescriptions for oxycodone issued to S.J.P., of Waverly, Ohio. *Id.* The Order alleged that Waverly, Ohio is "approximately 64 miles from Columbus" and that the prescriptions were issued by physicians who practiced "in Lees [sic] Summit, Missouri," as well as in Dayton and Portsmouth, Ohio, which are 78 and 92 miles, respectively, from Respondent. *Id.*

The Order thus alleged that Respondent "knew or should have known that the above dispensed controlled substances were likely to be diverted or used for other than legitimate medical purposes" and that "[b]y dispensing such prescriptions, [Respondent] failed to fulfill its corresponding responsibility for the proper dispensing of controlled substances." *Id.* at 3. Based on the above, I concluded that there was a "substantial likelihood that [Respondent] will continue to violate its corresponding responsibility to properly dispense controlled substances" and that Respondent's continued registration during the pendency of the proceeding "would constitute an imminent danger to the public health and safety." *Id.* I, therefore, ordered that Respondent's registration be suspended.

REDACTED

REDACTED

REDACTED

On May 18, 2010, the ALJ issued her Recommended Decision. Applying the public interest factors, *see* 21 U.S.C. 823(f), the ALJ concluded that the "record demonstrates that it is against the public interest for the Respondent to retain its controlled substances registration" and recommended that "Respondent's registration be revoked and any pending applications for renewal be denied." ALJ at 54.

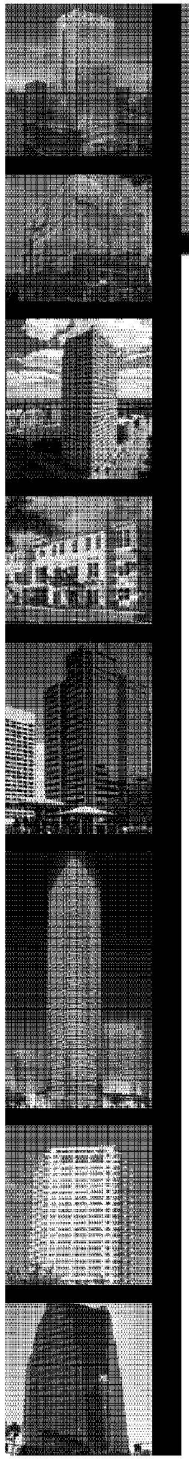
Under the first factor—the recommendation of the appropriate State licensing board or professional disciplinary authority—the ALJ found that "the Ohio Board of Pharmacy has not made a recommendation in this proceeding." *Id.* at 45. The ALJ further found, however, that on March 5, 2009, the Board had fined Mr. Fletcher and placed his license on probation because he "did not ensure, on three separate occasions, that a qualified person was at * * * Respondent to receive deliveries of controlled substances," which "were left at unsecure locations pending his arrival at the Respondent." *Id.* The ALJ concluded that this "security violation weighs in favor of revocation" of Respondent's registration. *Id.*

As to the second factor—Respondent's experience in dispensing controlled substances—the ALJ found that "Respondent ignored numerous 'red flags' when dispensing controlled substances to Dr. Volkman's patients." *Id.* at 46. In particular, the ALJ relied on the testimony and report of the Government's Expert that various patients of Volkman:

> (1) were driving long distances to have their prescriptions filled, (2) were receiving large volumes of controlled substances in the highest strength in each prescription, (3) were not receiving individualized therapy, for 75% of these patients received the same four drug 'cocktail,' (4) were paying large amounts of cash for their prescriptions, and (5) were receiving multiple narcotic pain killers on the same day.

Id.

Noting Agency precedent that "'[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescriptions,'" *id.* at 47 (quoting *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990)), the ALJ concluded that Respondent "clos[ed] a blind eye to these obvious red flags," and accordingly, "was not taking seriously its corresponding responsibility for these prescriptions" to



The Evolving Concept of Corresponding Responsibility

Quarles & Brady LLP

U.S. v. Hayes, 595 F. 2d 258 (1979)

- Facts that should have alerted the pharmacist that prescriptions were not issued for a medical purpose
  - Filling 34 prescriptions for Dilaudid for same individual in one month, and filling 101 prescriptions for the same person the following month
  - Prescriber was an alcoholic who moved frequently between temporary quarters
  - Prices charged for drugs were unusually high

U.S. v. Hayes, (1979)

- "Corresponding responsibility" does not require a pharmacist to practice medicine
- Verification of prescription by prescriber is not a safe harbor

U.S. v. Irwin, 661 F.2d 1063 (1981)

Elements of the offense of criminal distribution based on lack of "corresponding responsibility"

- Delivery of controlled substance
- Delivery of the drugs was other than for a legitimate medical purpose and in the usual course of professional practice
- Conduct was knowing and intentional

U.S. v. Irwin, 661 F.2d 1063 (1981)

A violation of the pharmacist's "corresponding responsibility" is not the same as filling prescriptions that lack the required form and content

U.S. v. Irwin, 661 F.2d 1063 (1981)

Facts relevant to conviction of pharmacist

- When government informant began receiving controlled substances frequently, defendant said, "you must be selling them."
- Pharmacist quadrupled what he previously charged when selling drugs to the informant
- Prescriptions were forged

U.S. v. Henry, 727 F.2d 1373 (1984)

- Facts that should have alerted the pharmacist that prescriptions were not issued for a medical purpose
  - Frequently filling prescriptions for same person under multiple names
  - Instructing purchaser on non-medical use of drug
  - Hearing purchaser state that drugs would be shared with others

Ralph J. Bertolino (1989)

- CSA requires use of common sense and professional judgment
- When suspicion is aroused as reasonable professionals, either by ambiguities in the prescription or sheer volume, pharmacists must refuse to dispense

Ralph J. Bertolino (1989)

- Facts supporting failure to exercise corresponding responsibility
  - The number of prescriptions issued by a small number of prescribers
  - The number of dosage units prescribed
  - The duration and pattern of the alleged treatment
  - The fact that Preludin was widely abused

Liberty Discount Drugs (1989)

- Dispensing pattern was indicative of diversion even for those with no pharmacy training
  - Alternating purchases of cough syrup by family members
  - Same day purchases by multiple family members
  - Regular purchases over a long period of time
- Pharmacist: “not my job” to detect because customers have right to get prescriptions filled

United Prescription Services (2007)

Pharmacy violated corresponding responsibility when it had ample evidence that prescriber was not acting in the usual course of professional practice

Medicine Shoppe (2008)

- Corresponding responsibility prohibits a pharmacist from filling a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose"
- "When prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes…."

Medicine Shoppe (2008)

- "When a customer presents a suspicious prescription, at a minimum, a pharmacist has a duty to verify the prescription with the prescriber."
- Verification by prescriber does not allow pharmacists to ignore evidence that gives "reason to believe" prescription was not issued for a legitimate medical purpose

Med. Shoppe v. DEA, *unpublished* (2008)

- "Corresponding responsibility means that a pharmacist is obligated to refuse to fill a prescription if he knows or has reason to know that the prescription was not written for a legitimate medical purpose"
- Pharmacist must use common sense and professional judgment

Med. Shoppe v. DEA, *unpublished* (2008)

- Facts proving pharmacist did not fulfill corresponding responsibility
  - Filled 100 prescriptions every other day issued by veterinarian whose state license and DEA registration were expired
  - Drugs prescribed by practitioner outside practitioner's normal practice area
  - Evidence that patients were doctor-shopping

Holiday CVS (2012)

Violation of "corresponding responsibility" in administrative case required

- Delivery of controlled substance
- A red flag was or should have been recognized
- The question raised by the red flag was not resolved ***conclusively*** prior to dispensing

Holiday CVS (2012)

The "irresolvable" red flags

- Prescriber in Fort Lauderdale, patient had out of state address, and patient paid cash for oxycodone 30 mg
- Same red flags + prescriptions filled in close sequence for several individuals from out of state

Holiday CVS (2012)

The "irresolvable" red flags

- Dispensing oxycodone 30 mg and 15 mg products to the same patient
- Prescribers whose prescribing pattern suggests a one size fits all concept

Physicians' Pharmacy (2012)

Corresponding responsibility apparently met by –

- Requiring diagnosis code
- Request prescriber to fax copy of prescription to pharmacy
- Use PDMP to look for doctor-shoppers
- Requiring presentation of state-issued I.D.
- Keeping a log of all controlled substances

Top Rx Pharmacy (2013)

Violation of "corresponding responsibility" in administrative case required

- Delivery of controlled substance
- A red flag was or should have been recognized
- The question raised by the red flag was not resolved ***conclusively*** prior to dispensing

Top Rx Pharmacy (2013)

Red flags based on state law

- Dispensing is unlawful if pharmacists knows or should know that prescription was issued outside a valid physician-patient relationship
- Can judge validity of physician-patient relationship based on manner
  - Manner in which prescriptions are received
  - Number of prescriptions for controlled substances issued by the practitioner
  - Number of patients receiving controlled substances

Top Rx Pharmacy (2013)

Red flags based on statements by pharmacy employees

"To the extent [the] statements constituted a red flag, [the pharmacy] should have stopped all controlled substances dispensing until resolved."

Top Rx Pharmacy (2013)

Conclusively resolving red flags

- Judged using "reasonable pharmacist standard"
- Steps necessary to resolve red flags are influenced by circumstancing giving rise to the red flags

Red Flags

- Individual has prescriptions for controlled substances from multiple doctors
- Patient receives more than one controlled substance that treat the same indications
- Patient seeks early refills
- Patient has prescriptions for large quantity or large doses of controlled substances

Red Flags

- Patients travel long distances from residence to reach prescriber or pharmacy
- Patient receives opiate, a benzodiazepine, and carisopridol ("cocktailized" dispensing)
- Lack of individualized dosing

Red Flags

- Filling multiple prescriptions for the strongest formulation
- Requests for early refills
- Doctor located 100 miles away from pharmacy (or any distance that is unreasonable)
- Large portion of prescriptions for controlled substances issued by one prescriber

Red Flags

- Failing to contact other pharmacists to inquire why they refuse to fill prescriptions issued by a particular prescriber
- Patients traveling in groups to pharmacy
- Large percentage of prescriptions are paid for in cash
- Cash payments in combination with other red flags

Red Flags

- Relying solely on prescriber's representation that prescription is legitimate
- Drug is inconsistent with prescriber's area of practice (fentanyl from dentist)
- Patient refer to drugs using street slangs (xanies, bars, purple drank, blues)

Red Flags

- People who are not regular patrons present prescriptions from same prescriber
- Customers receiving similar controlled substances have same address
- Family members receive prescriptions for controlled substances from same prescriber

Red Flags

- Action against prescriber by state boards or law enforcement
- Pharmacy patient profile reveals patient is receiving controlled substances from multiple prescribers at the same time
- Lack of a valid doctor-patient relationship

Resolving the Resolvable Red Flags

- Talk extensively with patient --question them if they are from out of the area
- Contact the prescriber
- Refuse to fill the prescription
- Use your instincts
- Use the PDMP

Resolving the Resolvable Red Flags

- Document all communications with the prescribing practitioner (?)
- Talk with other pharmacists in your area
- Be aware of local and national news regarding prescription drug abuse
- Report prescription to BOP/DEA

Resolving the Resolvable Red Flags

- Verify prescriber's DEA registration
- Conduct an internet search
- Evaluate appearance of the patient (in pain, under the influence of controlled substances?)

The Future of Corresponding Responsibility

- Likely that DEA will identify new red flags as diversion
- Red flags are likely to be based on suspicions and statements by employees and others

The Future of Corresponding Responsibility

- Continued deference to the agency by courts in criminal cases
  - Requirement to conclusively resolve red flags
  - Irresolvable red flags or combinations of red flags
- Likely that additional red flags or combination of red flags will be deemed irresolvable

The Four "Ps" of Corresponding Responsibility

- Prescriber
- Prescription
- Patient
- Product

Contact Information

You may contact Larry or Linden regarding this presentation or other DEA compliance matters by email or phone:

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http://www.deachronicles.com

Arizona Guidelines For Dispensing Controlled Substances

AzPA
Arizona Pharmacy Association

2013

Arizona Prescription Drug Misuse and Abuse Initiative

The abuse of prescription drugs is a serious social and health problem in the United States. Arizona is no exception to this problem. According to data from Arizona's Prescription Drug Monitoring Program, there are approximately 10 million Class II-IV prescriptions written and 524 million pills dispensed each year in Arizona. Prescription pain relievers accounted for over half of the drugs dispensed.

As the access and availability of these habit-forming drugs grows, so too does the likelihood of misuse, and moreover, the costly outcomes related to misuse and abuse. Arizona was ranked the 6th highest state in the country for prescription drug abuse, with over 13% of Arizona adults and almost 8% of Arizona youth reporting current misuse of controlled substances. Not surprisingly, Arizona has also seen a corresponding, and dramatic, increase in opioid-related cases in Emergency Departments and drug poisoning deaths involving prescription drugs.

As healthcare professionals, Pharmacists play a very critical role in helping Arizona solve the prescription drug misuse and abuse problem in our state. These guidelines are intended to help Dispensers reduce the inappropriate use of controlled substances while preserving the vital role of the Pharmacy to treat patients with medical conditions. These guidelines were developed at the Arizona Pharmacist Forum sponsored by the Arizona Pharmacy Association, the Arizona Criminal Justice Commission, the Arizona State Board of Pharmacy and the High Intensity Drug Trafficking Area Agency.

The work group was composed of members representing:

- Local Retail Pharmacies
- Corporate Pharmacies
- Midwestern University
- University of Arizona
- County and State Health Officials
- Insurance Companies
- The National Meth and Pharmaceutical Initiative
- Local Substance Abuse Community Coalitions

As defined by the Institute of Medicine, guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." As such, these guidelines are intended to provide general advice to the Pharmacist working in retail Pharmacies throughout Arizona. The Arizona Guidelines for Dispensing Controlled Substances should never be relied on as a substitute for proper assessment and professional judgment for the particular circumstances of each case.

Thank you for reviewing these Guidelines and doing your part to protect the health, safety and welfare of Arizona's citizens.

RECOMMENDATIONS

Arizona Guidelines for Dispensing Controlled Substances

1: Pharmacists should check the Arizona Prescription Drug Monitoring Program before dispensing controlled substances, and specifically in the following circumstances:

- Regular patients at least once per year
- Any prescription for Oxycodone 15mg or 30mg
- All Schedule II or Schedule III drugs for:
  - Every new or unknown patient
  - All weekend and late day prescriptions
  - Prescriptions written far from the location of the Pharmacy or the patient's residence
  - Any time suspicious behavior is noted (e.g., nervous, overly talkative, agitated, emotionally volatile, evasive, etc…for more information see Appendix A)
- Use clinical judgment in these situations:
  - Any prescription written for a controlled substance in high doses or high quantities
  - Any prescription considered an outlier to what is normally prescribed (use clinical judgment)
- Additional recommendations:
  - It is recommended that pharmacists document a note

in their patient's file including date, initials and action taken to indicate that the PDMP was checked

- It is recommended that all pharmacists in the pharmacy, including part-time "floaters" receive education on use of the PDMP

The following is the direct link to PDMP information:
http://www.azpharmacy.gov/CS-Rx_Monitoring/practioner_procedures.asp
For additional information on the PDMP please contact the Arizona State Board of Pharmacy at (602) 771-2744 or **dwright@azpharmacy.gov**

2: Pharmacists should use clinical judgment on the appropriateness of communicating with Prescribers prior to dispensing a controlled substance, but should specifically do so in the following circumstances:

- Pharmacist suspects a forged, altered or counterfeit prescription
- Patient is repeatedly requesting early refills of controlled substances
- Patient is specifically requesting early refills of Opioids, Benzodiazepines or Carisoprodol
- Patient presents with a high quantity from the Emergency Department
- Any time suspicious behavior is noted (e.g., nervous, overly talkative, agitated, emotionally volatile, evasive, etc....for more information, see Appendix A)
- It is recommended that pharmacists establish face-to-face contact with the Emergency Department Director, if they receive high traffic from ED patients
- It is recommended that pharmacists call the phone number for the prescriber listed in their computer vs. the phone number on the prescription to avoid false numbers on forged prescriptions

3: Pharmacists should use clinical judgment on the appropriateness of communicating with other pharmacies prior to dispensing a controlled substance, but should specifically contact other Pharmacies in the following circumstances:

- If you receive a prescription that has been denied by another pharmacist
- If you deny a patient a prescription, it is recommended that you call/fax all pharmacies within a 5 mile radius to alert them
- It is important to note that cross-communication between pharmacies regarding a patient's health and treatment is NOT a violation of HIPPA

4: Pharmacists should require a government issued identification for all new or unknown patients before dispensing any controlled substance.

- If you suspect a fake ID is involved, conduct the following verification steps (see Appendix B for more details):
  - Squeeze the ID to make sure the weight and rigidity matches AZ IDs
  - Look for squared edges (most IDs have rounded edges)
  - Using the pads of your fingers, lightly feel for bumps, ridges

and irregularities on the front and back surfaces of the ID
    - Check for font or coloration differences (e.g., different font style, improper bolding, lack of shading, spelling errors, or the wrong font size)
    - Check the front and back for words like secure, valid, genuine or credibility status (these are common false "security measures" placed on fake IDs)
    - Request another form of ID (e.g., a credit card), as people who present fake IDs are often reluctant to produce another form
- If you confirm a fake ID, do not dispense the prescription

5: Pharmacists should not fill a prescription if they believe it is forged, altered, or counterfeited

- Call the prescriber to verify first -- use the phone number for the provider in your computer vs. on the prescription
- Be familiar with the types of fraudulent prescriptions and characteristics of forged prescriptions (see Appendix C for details)
- Fill out a DEA FaxNet form for all fraudulent prescriptions: **http://azpharmacy.gov/pdfs/fax%20net.pdf.**
- If a pharmacist denies a prescription, it is recommended that the pharmacist notify other local pharmacists (in a 5 mile radius); again cross-communication between pharmacists is NOT a violation of HIPPA
- If you believe you have discovered a pattern of prescription abuse, contact your State Board of Pharmacy, your local DEA office, your local sheriff's office or police department -- reporting can be anonymous
- Be familiar with the law and your legal and ethical responsibilities; according to the DEA (see appendix A and C for details):
    - It is unlawful to knowingly dispense controlled substances for anything other than a "legitimate medical purpose"
    - There is no legal obligation to dispense a prescription, especially one of doubtful, questionable, or suspicious origin
    - To do so with a chemically dependent patient may violate federal or state provisions on maintenance of addiction, and you could be liable if the patient later injures himself or others
- Under these circumstances, it is safer to politely refuse to dispense the prescription and to refer the patient to his/her attending physician for further management. Document any such encounters in their patient files
- If possible, retain the prescription; however, even a fraudulent prescription is regarded as private property and should be returned promptly to the individual
- There is no legal requirement to contact the police regarding a suspected drug seeker; however, because a minority of drug seekers, particularly those who are chemically dependent, may resort to verbal abuse or acts of violence, it is advisable that you do so

6: Pharmacists should educate their patients about proper storage and proper disposal during the patient consultation prior to dispensing controlled substances.

- This is especially true if there are youth in the home, given that prescription drugs are now the 4th most used substance by teens and most report obtaining them in the home (Arizona Youth Survey)
- Storage tips should include never leaving any controlled substance out "in the open" in situations like kitchen counters, unlocked medicine cabinets, or even purses or handbags
- Disposal tips should include never flushing prescriptions down the toilet or throwing them in the trash
- Disposal tips should also include information on take-back events and permanent drop box locations
- If take-back events or drop boxes are unavailable, instruct your patients to use the DEA disposal guidelines and FDA tips:
  - Take the drugs out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter; then put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag
  - Before throwing out a medicine container, tell the patient to scratch out all identifying information on the prescription label to protect their identity and personal health information
  - Tell your patients to not share medication with friends, family or others and remind them that doing so could pose a serious health risk to someone
- It is encouraged that you use the information sheets available in Appendix D and E as handouts for patients; for more information, please see **www.DrugFreeAz.org/Rx**; and **http://www.deadiversion.usdoj.gov/drug_disposal/index.html**

LIST OF APPENDIXES

Appendix A: Identifying The Drug Seeking Patient In A Pharmacy

Chemically dependent patients often come to pharmacies for early refills of their prescriptions. These patients may appear to be experiencing

acute withdrawal symptoms and may become extremely agitated, tearful and violent if they cannot obtain their drug of choice, or a substitute.

Alternatively, patients who present with a lethargic, disinterested, perhaps giddy or overly friendly personality style, slurred speech and staggering gait may be intoxicated and seeking more drugs. An overly familiar presentation, intruding on an appropriate professional interpersonal space, or even covert or overt seductiveness should arouse suspicions.

A patient cannot be readily diagnosed as chemically dependent in a pharmacy setting. However, chemically dependent patients do exhibit diagnostic clues including the following:

SIGNS OF CHEMICAL DEPENDENCY AND DOCTOR SHOPPING	RED FLAG INDICATORS
Pupils – pinpoint or extremely dilated	Refuses or is reluctant to present identification
Droopy eyelids	Out-of-town patient or claims to be from out-of-town
Constant runny nose and rubbing of nose	Cash-paying patients or use insurance at times/pay cash at times
Complexion either pale or flushed	Very assertive
Excessive itching and scratching	Any telephone requests for narcotics
Sweating	Presents at times when prescriber cannot be reached
Tremors	Inordinate interest in the layout of the pharmacy
Rigid movements and muscle cramps	Appears to be in a hurry
Fearful and agitated (in withdrawal)	Tries to take control of the discussion
Emotionally volatile (in withdrawal)	Well versed in clinical terminology
Lethargic and disinterested (using drug)	Reports allergy to codeine, NSAIDs, or local anesthetics
Giddy and overly friend (using drug)	Very manipulative - they tell a very good story
Evasive answers	Inappropriate interpersonal space or seductiveness

HOW TO DEAL WITH A DRUG SEEKER

There is no legal obligation to dispense a prescription. To do so with a chemically dependent patient may violate federal or state provisions on maintenance of addiction. Moreover, if a patient is obviously intoxicated, then the pharmacist could be liable if he or she dispenses the medication and the patient later injures himself or others. Under these circumstances, it is safer to politely refuse to dispense the prescription and to refer the patient to his/her attending physician for further management. Document any such encounters in their patient files.

There is no legal requirement to contact the police regarding a suspected drug seeker; however, because a minority of drug seekers, particularly those who are chemically dependent, may resort to verbal abuse or acts of violence, it is advisable that you do so.

APPENDIX B: IDENTIFYING FAKE IDENTIFICATION

1) The easiest way to detect a fake ID is the visual and physical examination of the actual document. You must get the ID in hand to be able to feel it and properly examine it. There are four basic "feel" tests that will aid in this detection. The first is to check the rigidity of the card. In many cases, the material of the Fake ID is of a different weight/thickness than the real document. Simply giving the ID a squeeze will help you make that determination. The weight of the document will vary from state to state but will be consistent within the state and the style of the ID being examined.
2) The second test involves checking the edges of the ID. Most IDs have rounded edges due to the material. If the edges feel square, it is possible that the ID has a false front. If the edge feels square, a closer inspection should be completed. Typically, the squared edge is due to an overlay affixed to the front of the ID. This overlay is cut incorrectly and creates the squared edge. Feeling the front and back surfaces should also be done as part of the "feel tests". Using the pads of the fingers, lightly feel for bumps, ridges and irregularities that are not part of the normal ID.
3) The last of the "feel" tests is to check the corners of the ID. Real documents are made so that the face of the ID cannot be peeled up. To check this, the carder can simply try to split the ID using a fingernail. If the ID splits it is a good indicator that the document is not real. It is not uncommon to find false front IDs. The texture of the false front is at times, different. Individuals reluctant to remove IDs from carriers may be using this technique.
4) It is important to conduct a visual examination of the ID as well. This should include checking the overall appearance of the ID as well as the fonts and coloration patterns. It is not uncommon to see font differences between fake and real documents. This may include a totally different font style, improper bolding, lack of shading and the wrong size font. The colors may be of different shades or even the wrong color for the type of ID being shown. Spelling errors have also been noted on fake IDs.
5) Many fake IDs have their own security features that are inconsistent with the real documents. They may have symbols on them that are common to fake IDs. A seal of authenticity, eagle's head or flying eagles, skeleton keys, whole globes or three part globes and words like secure, valid and genuine have been regularly placed on the security plate of the fake IDs. It is important to know what should be appearing on the face of the ID. Again, the use of an ID checking guide can be very useful in making

that assessment and should be available to staff in every pharmacy. Costs of these guides will vary and in some cases they may be able to be obtained free from an alcohol distributer (e.g., Budweiser).

6) When doing the visual examination of the ID, carders should always remember to examine the back as well. Those manufacturing illegal IDs go to a great deal of effort to try to match the face of the ID but often fail to put the same effort onto the back. The reverse side of the ID may have information which does not even match the real document. In some cases the manufacturer will put information on the back designed to convince the person examining it that the document is real (e.g., "Card Credibility Status Defined"). While the document may look good, the fine print tells a different story. In some cases, they will also have embedded statements like "Not a Real ID" or "Not a Government ID" on the back.

APPENDIX C: PHARMACIST'S GUIDE TO PRESCRIPTION FRAUD

YOUR RESPONSIBILITIES:

The abuse of prescription drugs-- especially controlled substances--is a serious social and health problem in the United States. As a healthcare professional, you share responsibility for solving the prescription drug abuse and diversion problem.

- You have a legal responsibility to acquaint yourself with the state and federal requirements for dispensing controlled substances.
- You also have a legal and ethical responsibility to uphold these laws and to help protect society from drug abuse.
- You have a personal responsibility to protect your practice from becoming an easy target for drug diversion.
- You must become aware of the potential situations where drug diversion can occur and safeguards that can be enacted to prevent this diversion.

The dispensing pharmacist must maintain constant vigilance against forged or altered prescriptions. The law holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

WHAT IS CORRESPONDING RESPONSIBILITY?

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately looks the other way when there is reason to believe that the purported prescription has not been issued for a legitimate medical purpose, may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

TYPES OF FRAUDULENT PRESCRIPTIONS

Pharmacists should be aware of the various kinds of fraudulent prescriptions which may be presented for dispensing.

- Legitimate prescription pads are stolen from physicians' offices and prescriptions are written for fictitious patients.
- Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the physician's prescription.
- Some drug abusers will have prescription pads from a legitimate doctor printed with a different call back number that is answered by an accomplice to verify the prescription.
- Some drug abusers will call in their own prescriptions and give their own telephone number as a call back confirmation.
- Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions.

CHARACTERISTICS OF FORGED PRESCRIPTIONS

- Prescription looks "too good"; the prescriber's handwriting is too legible;
- Quantities, directions or dosages differ from usual medical usage;
- Prescription does not comply with the acceptable standard abbreviations or appear to be textbook presentations;
- Prescription appears to be photocopied;
- Directions written in full with no abbreviations;
- Prescription written in different color inks or written in different handwriting.

PRESCRIPTION NOT ISSUED FOR A LEGITIMATE MEDICAL PURPOSE

The following criteria may indicate that the purported prescription was not issued for a legitimate medical purpose.

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area.
- The patient appears to be returning too frequently. A prescription that should have lasted for a month in legitimate use, is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- Patient appears presenting prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- Numerous "strangers," people who are not regular patrons or residents of your community, suddenly show up with prescriptions from the same physician.

PREVENTION TECHNIQUES

- Know the prescriber and his or her signature;
- Know the prescriber's DEA registration number;
- Know the patient; and
- Check the date on the prescription order. Has it been presented to you in a reasonable length of time since the prescriber wrote it?

REPORTING ACTIONS

- When there is a question concerning any aspect of the prescription order, call the prescriber for verification or clarification.
- Should there be a discrepancy, the patient must have a plausible reason before the prescription medication is dispensed.
- Any time you are in doubt, you should request proper identification. Although this procedure isn't foolproof (identification papers can also be stolen or forged), it does increase the drug abuser's risk.
- If you believe that you have a forged, altered, or counterfeited prescription -- don't dispense it -- call your local police if possible.
- If you believe that you have discovered a pattern of prescription abuse, contact your State Board of Pharmacy or your local DEA office. Both DEA and state authorities consider retail-level diversion a priority issue.

Source/Author: DEA Diversion website

APPENDIX D: PATIENT EDUCATION

For printable forms, please see **http://azcjc.gov/ACJC.Web/Rx/default.aspx**

DRUGFREEAZ.org
The Partnership for a Drug-Free America, Arizona Affiliate

Teen Abuse of Prescription & Over-The-Counter Medicine Now an Epidemic

Good Medicine/Bad Behavior

Thousands of Arizona teenagers are intentionally abusing prescription medicines (pain relievers, tranquilizers, stimulants, sedatives, and over-the-counter cough medicines "to get high." According to the 2012 Arizona Youth Use Survey, 1 out of 4 12th graders report abusing prescription medicines to get high, and 1 out of 5 8th graders report abusing prescription medicine.

The high level of this behavior – called "pharming" – means it has become entrenched and "normalized." There are two factors are driving this epidemic:

Ease of access through a medicine cabinet at home or a friend's house, **and the internet.** 40% of teens **mistakenly believe that intentionally abusing Rx medicines is much safer than using so-called "street drugs."**

We can stop the abuse of prescription medicine. Please take the next step and dispose of unused medicine and safeguard your medicine cabinet at home. Please ask your friends and family to do the same.

To learn more about prescription drug abuse please visit **DrugFreeAz.org/Rx**

APPENDIX D: PATIENT EDUCATION

For printable forms, please see **http://azcjc.gov/ACJC.Web/Rx/default.aspx**

DRUGFREEAZ.org
The Partnership for a Drug-Free America, Arizona Affiliate

How to Dispose of Unused Medicines

Is your medicine cabinet filled with expired drugs or medications you no longer use? How should you dispose of them?

Most drugs can be thrown in the household trash, but consumers should take certain precautions before tossing them out, according to the Food and Drug Administration (FDA). A growing number of community-based "take-back" programs offer another safe disposal alternative.

Guidelines for Drug Disposal

The FDA worked with the White House Office of National Drug Control Policy to develop the first consumer guidance for proper disposal of prescription drugs. The federal guidelines are summarized here:

- Follow any specific disposal instructions on the drug label or patient information that accompanies the medication. Do not flush prescription drugs down the toilet.
- Take advantage of community drug take-back programs that allow the public to bring unused drugs to a central location for proper disposal. Call your city or county government's household trash and recycling service to see if a take-back program is available in your community. The Drug Enforcement Administration, working with state and local law enforcement agencies, is sponsoring National Prescription Drug Take Back Days (**www.deadiversion.usdoj.gov**) throughout the United States.
- If no instructions are given on the drug label and no take-back program is available in your area, throw the drugs in the household trash, but first:

- **Take them out of their original containers and mix them with an undesirable substance, such as used coffee grounds or kitty litter. The medication will be less appealing to children and pets, and unrecognizable to people who may intentionally go through your trash.**
- **Put them in a sealable bag, empty can, or other container to prevent the medication from leaking or breaking out of a garbage bag.**

FDA's Deputy Director of the Office of Compliance Lisa Bernstein, Pharm. D., J.D., offers some additional tips:

- Before throwing out a medicine container, scratch out all identifying information on the prescription label to make it unreadable. This will help protect your identity and the privacy of your personal health information.
- Do not give medications to friends. Doctors prescribe drugs based on a person's specific symptoms and medical history. A drug that works for you could be dangerous for someone else.
- When in doubt about proper disposal, talk to your pharmacist.

Bernstein says the same disposal methods for prescription drugs could apply to over-the-counter drugs as well.

Created by DrugFreeAZ.org and adapted from Consumer Health Information

TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Emergency Rule
LSA Document #13-_____(E)
DIGEST

Temporarily adds provisions under P.L. 185-2013 (SEA 246) regarding physicians prescribing opioids for chronic pain. Effective December 15, 2013.

SECTION 1. **This document establishes standards and protocols for physicians in the prescribing of controlled substances for pain management treatment. It is adopted under the authority of IC 25-22.5-13-2.**

SECTION 2. **(a) The definitions in this SECTION apply throughout this document.**

(b) "Chronic Pain" means a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

(c) "Controlled substances" has the meaning set forth in IC 35-48-1-9.

(d) "Morphine Equivalent Dose" means a conversion of various opioids to a standardized dose of morphine by the use of accepted conversion tables.

(e) "Opioid" means any of various narcotics containing opium or one or more of its natural or synthetic derivatives.

(f) "Outset of an opioid treatment plan" means that a patient has been prescribed opioids as described in SECTION 3(c) of this document and therefore the provisions stated in SECTION 3(a) of this document become applicable to that patient.

(g) "Terminal" means a condition caused by injury, disease, or illness from which, to a reasonable degree of medical certainty:

(1) there can be no recovery; and

(2) progression to death can be anticipated as an eventual consequence of that condition.

SECTION 3. **(a) This SECTION and SECTIONS 4 through 11 of this document establish requirements concerning the use of opioids for chronic pain management for patients.**

(b) Notwithstanding subsection (a), this SECTION and SECTIONS 4 through 11 of this document shall not apply to the use of opioids for chronic pain management for the following:

(1) Patients with a terminal condition.

(2) Residents of a health facility licensed under IC 16-28.

(3) Patients enrolled in a hospice program licensed under IC 16-25.

(4) Patients enrolled in an inpatient or outpatient palliative care program of a hospital licensed under IC 16-21 or a hospice licensed under IC 16-25.

However, a period of time that a patient who was, but is no longer, a resident or patient as described in subdivisions (2) through (4), shall be included in the calculations under subsection (c).

(c) The requirements in the SECTIONS identified in subsection (a) only apply if a patient has been prescribed:

(1) more than sixty (60) opioid-containing pills a month; or

(2) a morphine equivalent dose of more than fifteen (15) milligrams per day;

for more than three (3) consecutive months.

(d) Because the requirements in the SECTIONS identified in subsection (a) do not apply until the time stated in subsection (c), the initial evaluation of the patient for the purposes of SECTIONS 4, 7(a) and 8(a) shall not be required to take place until that time.

(e) Notwithstanding subsection (d), the physician may undertake those actions earlier than required if the physician deems it medically appropriate and if those actions meet the requirements a further initial evaluation is not required. If the physicians conducts actions earlier than required under this subsection, any subsequent requirements are determined by when the initial evaluation would have been required and not at the earlier date it actually was conducted.

SECTION 4. (a) The physician shall do the physician's own evaluation and risk stratification of the patient by doing the following in the initial evaluation of the patient:(1) Performing an appropriately focused history and physical exam and obtain or order appropriate tests, as indicated.

(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physicians understanding of the patient's chronic pain problem, including past treatments, and documenting this effort.

(3) Asking the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns.

(4) Assessing both the patient's mental health status and risk for substance abuse using available validated screening tools.

(5) After completing the initial evaluation, establishing a working diagnosis and tailoring a treatment plan to meaningful and functional goals with the patient reviewing them from time to time.

(b) Where medically appropriate, the physician shall utilize non-opioid options instead of or in addition to prescribing opioids.

SECTION 5. The physician shall discuss with the patient the potential risks and benefits of opioid treatment for chronic pain, as well as expectations related to prescription requests and proper medication use. In doing so, the physician shall:

(1) Where alternative modalities to opioids for managing pain exist for a patient, discuss them with the patient.

(2) Provide a simple and clear explanation to help patients understand the key elements of their treatment plan.

(3) Counsel women between the ages of 14 and 55 with child bearing potential about the risks to the fetus when the mother has been taking opioids while pregnant. Such described risks shall include fetal opioid dependency and neonatal abstinence syndrome (NAS).

(4) Together with the patient, review and sign a "Treatment Agreement", which shall include at least the following:

(A) The goals of the treatment.

(B) The patient's consent to drug monitoring testing.

(C) The physician's prescribing policies which must include at least:

(i) a requirement that the patient take the medication as prescribed; and

(ii) a prohibition of sharing medication with other individuals.

(D) A requirement that the patient inform the physician about any other controlled substances prescribed or taken.

(E) The granting of permission to the physician to conduct random pill counts.

(F) Reasons the opioid therapy may be changed or discontinued by the physician.

A copy of the treatment agreement shall be retained in the patient's chart.

SECTION 6. **(a) Physicians shall not prescribe opioids for patients without periodic scheduled visits. Visits for patients with a stable medication regimen and treatment plan shall occur face to face at least once every four (4) months. More frequent visits may be appropriate for patients working with the physician to achieve optimal management. For patients requiring changes to the medication and treatment plan, if changes are prescribed by the physician, the visits required by this subsection shall be scheduled at least once every two (2) months until the medication and treatment has been stabilized.**

(b) During the visits required by subsection (a) the physician shall evaluate patient progress and compliance with the patient's treatment plan regularly and set clear expectations along the way (such as, attending physical therapy, counseling or other treatment options).

SECTION 7. **At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall run an INSPECT report on that patient under IC 35-48-7-11.1(d)(4) and document in the patient's chart whether the INSPECT report is consistent with the physician's knowledge of the patient's controlled substance use history.**

SECTION 8. (a) **At the outset of an opioid treatment plan, and at least annually thereafter, a physician prescribing opioids for a patient shall perform or order a drug monitoring test, which must include a confirmatory test, on the patient.**

(b) If the test required under subsection (a) reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised plan and discussion with the patient must be recorded in the patient's chart.

SECTION 9. **When a patient's opioid dose reaches a morphine equivalent dose of more than sixty (60) milligrams per day, a face-to-face review of the treatment plan and patient evaluation must be scheduled, including consideration of referral to a specialist. If the physician elects to continue providing opioid therapy at a morphine equivalent dose of more than sixty (60) milligrams per day, the physician must develop a revised assessment and plan for ongoing treatment. The revised assessment and plan must be documented in the patient's chart, including an assessment of increased risk for adverse outcomes, including death, if the physician elects to provide ongoing opioid treatment.**

SECTION 10. (a) IC 25-27.5-5 addresses the scope of practice of physician assistants in their dependent practice under supervising physicians including limiting the duties and responsibilities of physician assistants to those that are delegated by the supervising physician and that are within the supervising physician's scope of practice. IC 25-27.5-6 addresses supervisory responsibilities of the supervising physician, or when applicable, a physician designee. The prescribing of opioids for chronic pain management as regulated by this document falls within the requirements on supervising physicians, or when applicable, on physician designees, under IC 25-27.5-5 and IC 25-27.5-6 including appropriate delegating of duties and responsibilities to physician assistants and appropriate supervision of physician assistants.

(b) IC 25-23-1-19.4 through IC 25-23-1-19.8, and 848 IAC 5, address the practice of advanced practice nurses with prescriptive authority in collaboration with a physician. The prescribing of opioids for chronic pain management as regulated by this document falls within the requirements on collaborating physicians regarding the prescriptive authority for advanced practice nurses under IC 25-23-1-19.4 though IC 25-23-1-19.8 and 848 IAC 5.

SECTION 11. (a) Initial running of an INSPECT report as required under SECTION 7 of this document shall not be required for any patient who fell within the scope of SECTION 3(c) of this document before December 15, 2013. Initial conducting of a drug monitoring test as required under SECTION 8(a) of this document shall not be required for any patient who fell within the scope of SECTION 3(c) of this document before January 1, 2015. However, all other requirements of this document apply to these patients; that is, every requirement except for the initial running of the INSPECT report and the initial or annual conducting of a drug monitoring test.

(b) Notwithstanding subsection (a) and SECTION 7 of this document, the first running of an annual INSPECT report under SECTION 7 of this document shall not be required to be conducted before November 1, 2014. Nothing about this subsection shall be construed to prohibit a physician from running a report sooner than required by this subsection.

(c) Notwithstanding SECTION 8(a) of this document, the first conducting of an annual drug monitoring test under SECTION 8(a) of this document shall not be required to be conducted before January 1, 2015. Nothing about this subsection shall be construed to prohibit a physician from conducting a test sooner than required by this subsection.

SECTION 12. SECTIONS 1 through 11 of this document take effect December 15, 2013.

TITLE 844 MEDICAL LICENSING BOARD OF INDIANA

Emergency Rule
LSA Document #13-_____(E)
DIGEST

Temporarily adds provisions regarding administrative authorizations to examine controlled substances prescribing records.

SECTION 1. **(a) This document establishes standards and procedures for the medical licensing board to authorize, where appropriate, the attorney general to examine a physician's records and controlled substances inventory and materials to investigate the physician's controlled substances prescribing practices and the physician's compliance with IC 25-22.5, IC 25-1-9, and 844 IAC in relation to controlled substances prescribing activities.**

(b) Nothing in this document shall be interpreted or construed to abrogate, eliminate, reduce, restrict, or replace existing provisions authorizing the attorney general to issue subpoenas or civil investigative demands to investigate possible violations of IC 25-22.5, IC 25-1-9, and 844 IAC.

SECTION 2. **(a) The definitions in this SECTION apply throughout this document.**

(b) All terms which are defined in IC 25-22.5 and IC 35-48 shall have the same meanings as they are so defined when used in this document.

(c) "Board" refers to the medical licensing board of Indiana established by IC 25-22.5-2-1.

(d) "Controlled substance" has the meaning set forth in IC 35-48-1-9.

(e) "Controlled substance registration" refers to registration required and permitted by IC 35-48-3.

(f) "OAG" refers to the office of attorney general.

(g) "Examination authorization" means an order issued by the board directing the OAG to examine records as specified in the order.

SECTION 3. **(a) The OAG may file a verified petition with the board seeking an examination authorization.**

(b) Subject to the provisions of this document, the board may issue an examination authorization if the board believes that the authorization is necessary for the OAG to conduct an investigation of a physician's controlled substance prescribing practices through review of relevant records.

(c) Examination authorizations may not be sought or issued for the purpose of unreasonably interfering with a physician's regular practice operations or for the purpose of imposing undue burden or expense on the physician.

SECTION 4. **(a) The board may designate an individual member for purposes of reviewing a verified petition filed by the OAG and issuing an examination authorization.**

(b) The board may designate an individual member for purposes of responding to a petition for modification, limitation, or discontinuance of an examination conducted pursuant to an examination authorization.

SECTION 5. (a) The board may issue an examination authorization permitting examination of records of a physician with a controlled substance registration or a physician engaging in activities for which a controlled substance registration is required.

(b) The OAG may petition the board for an examination authorization if the OAG has a good faith reason to believe that a physician may have violated or is likely to violate provisions of any statute or rule concerning the prescribing, dispensing, or administering of a controlled substance.

(c) A verified petition filed under this document shall include the following:

(1) facts establishing a good faith reason to believe that a violation of an applicable controlled substance prescribing, dispensing, or administrative statute or rule may have occurred or is likely to occur;

(2) an explanation of why the examination authorization is necessary to protect consumers or patients or to respond to a clear and immediate danger to public health and safety, including why issuance of a subpoena is not believed to be sufficient or appropriate under the circumstances;

(3) a description of the records or categories of records to be examined in enough specificity to allow the respondent physician to identify the documents at issue;

(4) a general description of the location or locations where the records are maintained or believed to be maintained; and

(5) a statement confirming that the request for access complies with 45 CFR § 164.512(f)(1)(ii)(C).

(d) After reviewing a verified petition filed under this rule, the board may issue an examination authorization. The examination authorization shall authorize the OAG to immediately inspect and copy records maintained by the physician concerning the prescribing, dispensing, or administering of a controlled substance.

(e) A physician that is the subject of an examination authorization issued by the board pursuant to this rule shall comply with the examination authorization and cooperate with the attorney general's reasonable efforts to carry out the examination authorization.

(f) In carrying out an examination authorization, the records authorized for examination by the board shall be produced to the OAG by the respondent physician in either printed format or in electronic format as agreed upon by the parties. If the parties cannot agree as to the format of production, the respondent physician shall produce the records in printed format.

(g) The OAG may not require production of records in electronic format under subsection (f) of this SECTION if they are not created or maintained in electronic format. If records are to be produced in electronic format, the OAG may specify that they shall be produced in either native format with all software necessary to read the electronic records, or in a complete, unencrypted manner that is easily readable without the use of proprietary software.

(h)Proof of license agreement preventing a respondent physician's compliance with subsection (f) of this SECTION is to be provided at the time the OAG executes an examination authorization; any such license agreement is subject for review as to authenticity by the OAG. If the agreement is found to be authentic and prevents a respondent physician's compliance with subsection (f) of this SECTION, the physician will not be considered noncompliant as to the electronic production of records but will however, be required to produce the records in printed format.

(i) Provisions regarding payment for copies in the Indiana Rules of Trial Procedure are applicable to copies made pursuant to an examination authorization; however, these provisions do not prohibit the board from ordering reimbursement of costs as provided under IC 25-1-9.

SECTION 6. (a) Every examination authorization issued under this document shall be in writing and include the following:

(1) requirements for the OAG to execute the authorization during the normal business hours of the physician's practice, unless a narrower timeframe is specified by the board;

(2) requirements for the OAG to execute the authorization within ten (10) business days of issuance, unless otherwise specified by the board;

(3) procedures that shall be followed by the OAG in conducting the examination to avoid unreasonable and unnecessary interference with the operation of the physician or the health care provider for which the physician works;

(4) notice to the physician of the physician's rights, including:

(A) the right to be present and observe the examination and copying by the OAG, and the right to make an accounting of records examined and copied by the OAG;

(B) the right to continue to conduct its health care practice without unreasonable and unnecessary interference by the OAG during the examination;

(C) the right to consult with legal counsel in relation to rights specified in this rule and other applicable rights and remedies;

(D) the right to petition the board for an order directing the OAG to modify, limit, or discontinue an examination conducted pursuant to this document if the physician believes that the examination is being carried out in a manner that is unreasonable or oppressive.

(5) notice to the physician that failure to cooperate with the examination authorization and that destruction, alteration, or removal of records that are the subject of the examination authorization may result in administrative sanctions by the board.

(6) requirements for the OAG to preserve the integrity of the physicians' original records.

(b) If the OAG has knowledge that the physician who is the subject of an examination authorization issued under this rule has retained an attorney to provide legal counsel in relation to pending consumer complaints that are being investigated, the OAG shall provide notice to the attorney upon execution of the examination authorization; however, the physician's representation by legal counsel shall not delay the physician's requirement to immediately comply with SECTION 5(e) of this document.

SECTION 7. (a) A physician may file a petition with the board requesting that the board:

(1) modify the terms or scope of the examination authorization that the board previously issued;

(2) limit the terms or scope of an examination authorization that the board previously issued; or

(3) direct the OAG to discontinue an examination being conducted pursuant to an examination authorization that the board previously issued.

(b) In a petition filed under subsection (a) of this SECTION, a physician shall set forth reasons why the examination authorization should be modified, limited, or discontinued.

(c) Unless the board issues a temporary stay, the OAG's ability to continue conducting an examination pursuant to an examination authorization is not limited or affected during the pendency of the board's review of a petition by a physician under subsection (a) of this SECTION.

(d) The board may order the modification, limitation, or discontinuance of an examination authorization if the board finds that the physician has demonstrated any of the following:

(1) the OAG has exceeded the scope or terms of the examination authorization;

(2) the OAG has carried out the examination authorization in a manner that unreasonably interferes with the operation of the physician; or

(3) that the examination is no longer necessary for the OAG to conduct an investigation of a physician's controlled substance prescribing practices.

(e) An order modifying, limiting, or discontinuing an examination authorization shall not be construed to require the OAG to return or disregard information and copies of records properly obtained pursuant to the examination authorization before its modification, limitation, or discontinuance. However, the OAG may not use records obtained by exceeding the scope of an examination authorization in a disciplinary proceeding involving the licensee. Records improperly obtained shall be returned to the physician or destroyed by the OAG based on agreement of the parties.

SECTION 8. (a) The board may consider failure to comply with an examination authorization issued under this rule as a violation of IC 25-1-9-4(a)(3) when a physician who is the subject of an examination authorization issued by the board pursuant to this rule:

(1) fails to comply with the examination authorization; or

(2) refuses to comply with the examination authorization.

(b) The board may take action under subsection (a) of this SECTION after a hearing if:

(1) the OAG has brought a disciplinary action against the physician seeking sanctions under IC 25-1-9; or

(2) the board has issued an order requiring the physician to show cause why the board should not impose disciplinary sanctions against the physician under IC 25-1-9.

SECTION 9. (a) An examination authorization issued by the board pursuant to this document shall not be considered to constitute "agency action" or "final agency action" as those terms are defined in IC 4-21.5-1-4 and IC 4-21.5-1-6 of the Administrative Orders and Procedures Act.

(b) The board has discretion to schedule a hearing to consider a petition for an examination authorization filed by the OAG. Nothing in this document shall be construed or interpreted to require a hearing or to provide a physician with hearing rights in relation to a petition filed by the OAG.

(c) The board has discretion to schedule a hearing to consider a petition filed by a physician under SECTION 7(a) of this document. Nothing in this document shall be construed or interpreted to

require a hearing or to provide a physician with hearing rights in relation to a petition filed by the physician.

(d) A petition for judicial review of an examination authorization under IC 4-21.5-5 may not be filed by a physician before:

(1) all other available administrative remedies have been exhausted; and

(2) the board takes action to impose disciplinary sanctions against the physician under IC 25-1-9.

SECTION 10. (a) Records relating to the following are subject to the confidentiality provisions, limitations, and exceptions in IC 25-1-7-10:

(1) verified petitions requesting issuance of an examination authorization;

(2) examination authorizations issued by the board;

(3) petitions filed by physicians under SECTION 7(a) of this document; and

(4) orders issued by the board modifying, limiting, or terminating examination authorizations under SECTION 7(e) of this document.

(b) Hearings held under SECTION 9 of this document are subject to IC 5-14-1.5, the open door law.

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